

## PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION  
(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents  
 United States Patent and Trademark  
 Office  
 Box PCT  
 Washington, D.C.20231  
 ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 29 March 2000 (29.03.00)	
International application No. PCT/AU99/00691	Applicant's or agent's file reference 2208737/TDO
International filing date (day/month/year) 26 August 1999 (26.08.99)	Priority date (day/month/year) 27 August 1998 (27.08.98)
<b>Applicant</b> KOLA, Ismail et al	

1. The designated Office is hereby notified of its election made:

in the demand filed with the International Preliminary Examining Authority on:

25 February 2000 (25.02.00)

in a notice effecting later election filed with the International Bureau on:

\_\_\_\_\_

2. The election  was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No.: (41-22) 740.14.35	Authorized officer  Jean-Marc Vivet  Telephone No.: (41-22) 338.83.38
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PATENT COOPERATION TREATY

WEDNESDAY 8 MARCH 2000

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To: Agent :

DAVIES COLLISON CAVE  
1 Little Collins Street  
MELBOURNE VIC 3000

NOTIFICATION OF RECEIPT  
OF DEMAND BY COMPETENT INTERNATIONAL  
PRELIMINARY EXAMINING AUTHORITY  
(PCT Rule 59.3(e) and 61.1(b), first sentence  
and Administrative Instructions, Section 601(a))

Date of mailing 7 MAR 2000  
(day/month/year) (7/3/00)

Applicant's or agent's file reference  
2208737

IMPORTANT NOTIFICATION

International application No.  
PCT/AU99/00691

International filing date (day/month/year)  
26 AUG 1999 (26/8/99)

Priority date (day/month/year)  
27 AUG 1998 (27/8/98)

Applicant

Monash University (et al.)

1. The applicant is hereby **notified** that this International Preliminary Examining Authority considers the following date as the date of receipt of the demand for international preliminary examination of the international application:

25 FEB 2000 (25/2/00)

2. That date of receipt is:

the actual date of receipt of the demand by this Authority (Rule 61.1(b)).  
 the actual date of receipt of the demand on behalf of this Authority (Rule 59.3(c)).  
 the date on which this Authority has, in response to the Invitation to correct defects in the demand (Form PCT/IPEA/404), received the required corrections.

3.  **Attention:** That date of receipt is **AFTER** the expiration of 19 months from the priority date. Consequently, the election(s) made in the demand does (do) not have the effect of postponing the entry into the national phase until 30 months from the priority date (or later in some Offices) (Article 39(1)). Therefore, the acts for entry into the national phase must be performed within 20 months from the priority date (or later in some Offices) (Article 22). For details, see the *PCT Applicant's Guide, Volume II*.

(If applicable) This notification confirms the information given by telephone, facsimile transmission or in person on:

4. Only where paragraph 3 applies, a copy of this notification has been sent to the International Bureau.

Name and mailing address of the IPEA/AU  
AUSTRALIAN PATENT OFFICE  
PO BOX 200, WODEN ACT 2606, AUSTRALIA  
E-mail: pct@ipaaustralia.gov.au  
Facsimile No. 02 6285 3929

Authorized officer

MR SEAN McLACHLAN  
02 6283 2357

Telephone No.



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : C12N 15/12, C07K 14/435, 14/47, 14/475, A61K 39/395, 38/17		A1	(11) International Publication Number: <b>WO 00/12695</b> (43) International Publication Date: 9 March 2000 (09.03.00)
(21) International Application Number: PCT/AU99/00691		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).	
(22) International Filing Date: 26 August 1999 (26.08.99)			
(30) Priority Data: PP 5512 27 August 1998 (27.08.98) AU PP 6252 30 September 1998 (30.09.98) AU			
(71) Applicant (for all designated States except US): MONASH UNIVERSITY [AU/AU]; Monash Medical Centre, Level 5, 246 Clayton Road, Clayton, VIC 3168 (AU).			
(72) Inventors; and		Published	
(75) Inventors/Applicants (for US only): KOLA, Ismail [AU/AU]; 593 Orrong Road, Armadale, VIC 3143 (AU). ZHOU, Jiong [AU/AU]; 5 Valerie Court, Vermont South, VIC 3133 (AU).		With international search report.	
(74) Agents: SLATTERY, John, M. et al.; Davies Collison Cave, 1 Little Collins Street, Melbourne, VIC 3000 (AU).			

(54) Title: NOVEL THERAPEUTIC MOLECULES AND USES THEREOF

## (57) Abstract

The present invention relates generally to novel molecules capable of, *inter alia*, controlling cellular functional activity such as proliferation, differentiation and/or transcriptional regulation and to genetic sequences encoding same. More particularly, the present invention relates to novel members of the ETS family of proteins, referred to herein as "ELF5", and to genetic sequences encoding same. The molecules of the present invention are useful, for example, in therapy, diagnosis, antibody generation and as a screening tool for agents capable of modulating transcriptional events during cellular functioning such as in tumorigenesis.

## PATENT COOPERATION TREATY

PCT

NOTICE INFORMING THE APPLICANT OF THE  
COMMUNICATION OF THE INTERNATIONAL  
APPLICATION TO THE DESIGNATED OFFICES

(PCT Rule 47.1(c), first sentence)

From the INTERNATIONAL BUREAU

To:

SLATTERY, John, M.  
Davies Collison Cave  
1 Little Collins Street  
Melbourne, VIC 3000  
AUSTRALIA

TUESDAY 21 MAR 2000

Date of mailing (day/month/year) 09 March 2000 (09.03.00)			
Applicant's or agent's file reference 2208737/TDO		IMPORTANT NOTICE	
International application No. PCT/AU99/00691	International filing date (day/month/year) 26 August 1999 (26.08.99)	Priority date (day/month/year) 27 August 1998 (27.08.98)	
Applicant MONASH UNIVERSITY et al			

1. Notice is hereby given that the International Bureau has communicated, as provided in Article 20, the international application to the following designated Offices on the date indicated above as the date of mailing of this Notice:

AU,CN,EP,JP,KP,KR,US

In accordance with Rule 47.1(c), third sentence, those Offices will accept the present Notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

2. The following designated Offices have waived the requirement for such a communication at this time:

AE,AL,AM,AP,AT,AZ,BA,BB,BG,BR,BY,CA,CH,CR,CU,CZ,DE,DK,DM,EA,EE,ES,FI,GB,GD,GE,GH,  
GM,HR,HU,ID,IL,IN,IS,KE,KG,KZ,LC,LK,LR,LS,LT,LU,LV,MD,MG,MK,MN,MW,MX,NO,NZ,OA,PL,  
PT,RO,RU,SD,SE,SG,SI,SK,SL,TJ,TM,TR,TT,UA,UG,UZ,VN,YU,ZA,ZW

The communication will be made to those Offices only upon their request. Furthermore, those Offices do not require the applicant to furnish a copy of the international application (Rule 48.1(a-bis)).

3. Enclosed with this Notice is a copy of the international application as published by the International Bureau on 09 March 2000 (09.03.00) under No. WO 00/12695

## REMINDER REGARDING CHAPTER II (Article 31(2)(a) and Rule 54.2)

If the applicant wishes to postpone entry into the national phase until 30 months (or later in some Offices) from the priority date, a demand for international preliminary examination must be filed with the competent International Preliminary Examining Authority before the expiration of 19 months from the priority date.

It is the applicant's sole responsibility to monitor the 19-month time limit.

Note that only an applicant who is a national or resident of a PCT Contracting State which is bound by Chapter II has the right to file a demand for international preliminary examination.

## REMINDER REGARDING ENTRY INTO THE NATIONAL PHASE (Article 22 or 39(1))

If the applicant wishes to proceed with the international application in the national phase, he must, within 20 months or 30 months, or later in some Offices, perform the acts referred to therein before each designated or elected Office.

For further important information on the time limits and acts to be performed for entering the national phase, see the Annex to Form PCT/IB/301 (Notification of Receipt of Record Copy) and Volume II of the PCT Applicant's Guide.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No. (41-22) 740.14.35	Authorized officer  J. Zahra  Telephone No. (41-22) 338.83.38
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The demand must be filed, along with the corresponding International Preliminary Examining Authority, in the language of the International Preliminary Examining Authority, or in a language more authorising and convenient with the one chosen by the applicant. The language of inspection code of that authority may be indicated by the applicant on the line 5, IPEA.

# PCT

## CHAPTER II

### DEMAND

under Article 31 of the Patent Cooperation Treaty:  
The undersigned requests that the international application specified below be the subject of international preliminary examination according to the Patent Cooperation Treaty and hereby elects all eligible States (except where otherwise indicated).

For International Preliminary Examining Authority use only

Identification of IPEA	Date of receipt of DEMAND
<b>Box No. I IDENTIFICATION OF THE INTERNATIONAL APPLICATION</b>	
International application No. PCT/AU99/00691	International filing date (day/month/year) (26.08.1999) 26 August, 1999
(Earliest) Priority date (day/month/year) (27.08.1998) 27 August, 1998	
Title of invention <b>NOVEL THERAPEUTIC MOLECULES AND USES THEREFOR</b>	
<b>Box No. II APPLICANT(S)</b>	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) MONASH UNIVERSITY Monash Medical Centre Level 5 246 Clayton Road Clayton 3168 Victoria, Australia	
Telephone No.:	
Facsimile No.:	
Telex/Teletype No.:	
State (that is, country) of nationality: <b>AUSTRALIA</b>	State (that is, country) of residence: <b>AUSTRALIA</b>
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) KOLA, Ismail 593 Orrong Road Armadale 3143 Victoria Australia	
State (that is, country) of nationality: <b>AUSTRALIA</b>	
State (that is, country) of residence: <b>AUSTRALIA</b>	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) ZHOU, Jiong 5 Valerie Court Vermont South 3133 Victoria Australia	
State (that is, country) of nationality: <b>Australia</b>	State (that is, country) of residence: <b>Australia</b>
<input type="checkbox"/> Further applicants are indicated on a continuation sheet.	

## Box No. III AGENT OR COMMON REPRESENTATIVE: OR ADDRESS FOR CORRESPONDENCE

The following person is  agent  common representative

and  has been appointed earlier and represents the applicant(s) also for international preliminary examination.

is hereby appointed and any earlier appointment of (an) agent(s)/common representative is hereby revoked.

is hereby appointed, specifically for the procedure before the International Preliminary Examining Authority, in addition to the agent(s)/common representative appointed earlier.

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

SLATTERY, John M  
CAINE, Michael J  
HUNTSMAN, Peter H

DAVIES COLLISON CAVE  
1 Little Collins Street  
Melbourne 3000  
Victoria  
Australia

Telephone No.:

+61 3 9254 2777

Facsimile No.:

+61 3 9254 2770

Teleprinter No.:

Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

## Box No. IV BASIS FOR INTERNATIONAL PRELIMINARY EXAMINATION

## Statement concerning amendments:\*

1. The applicant wishes the international preliminary examination to start on the basis of:

the international application as originally filed

the description  as originally filed

as amended under Article 34

the claims  as originally filed

as amended under Article 19 (together with any accompanying statement)

as amended under Article 34

the drawings  as originally filed

as amended under Article 34

2.  The applicant wishes any amendment to the claims under Article 19 to be considered as reversed.

3.  The applicant wishes the start of the international preliminary examination to be postponed until the expiration of 20 months from the priority date unless the International Preliminary Examining Authority receives a copy of any amendments made under Article 19 or a notice from the applicant that he does not wish to make such amendments (Rule 69.1(d)). (This check-box may be marked only where the time limit under Article 19 has not yet expired.)

\* Where no check-box is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended.

Language for the purposes of international preliminary examination: English

which is the language in which the international application was filed.

which is the language of a translation furnished for the purposes of international search.

which is the language of publication of the international application.

which is the language of the translation (to be) furnished for the purposes of international preliminary examination.

## Box No. V ELECTION OF STATES

The applicant hereby elects all eligible States (that is, all States which have been designated and which are bound by Chapter II of the PCT)

excluding the following States which the applicant wishes not to elect:

## Box No. VI CHECK LIST

The demand is accompanied by the following elements, in the language referred to in Box No. IV, for the purposes of international preliminary examination:

1. translation of international application	:	sheets	<input type="checkbox"/>	<input type="checkbox"/>
2. amendments under Article 34	:	sheets	<input type="checkbox"/>	<input type="checkbox"/>
3. copy (or, where required, translation) of amendments under Article 19	:	sheets	<input type="checkbox"/>	<input type="checkbox"/>
4. copy (or, where required, translation) of statement under Article 19	:	sheets	<input type="checkbox"/>	<input type="checkbox"/>
5. letter	:	sheets	<input type="checkbox"/>	<input type="checkbox"/>
6. other (specify)	:	sheets	<input type="checkbox"/>	<input type="checkbox"/>

For International Preliminary Examining Authority use only

received      not received

The demand is also accompanied by the item(s) marked below:

1. <input type="checkbox"/> fee calculation sheet	4. <input type="checkbox"/> statement explaining lack of signature
2. <input type="checkbox"/> separate signed power of attorney	5. <input type="checkbox"/> nucleotide and or amino acid sequence listing in computer readable form
3. <input type="checkbox"/> copy of general power of attorney; reference number, if any:	6. <input type="checkbox"/> other (specify):

## Box No. VII SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand).

.....  
SLATTERY, John M  
for and on behalf of the  
applicant(s).

## For International Preliminary Examining Authority use only

## 1. Date of actual receipt of DEMAND:

## 2. Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b):

3.  The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and item 4 or 5, below, does not apply.

The applicant has been informed accordingly.

4.  The date of receipt of the demand is WITHIN the period of 19 months from the priority date as extended by virtue of Rule 80.5.

5.  Although the date of receipt of the demand is after the expiration of 19 months from the priority date, the delay in arrival is EXCUSED pursuant to Rule 82.

## For International Bureau use only

Demand received from IPEA on:

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 2208737/TAO	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/AU 99/00691	International filing date (day/month/year) 26 August 1999	(Earliest) Priority Date (day/month/year) 27 August 1998
<b>Applicant</b> 1. MONASH UNIVERSITY 2. KOLA, Ismail 3. ZHOU, Jiong		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 5 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international application, the international search was carried out on the basis of the sequence listing:

contained in the international application in written form.

filed together with the international application in computer readable form.

furnished subsequently to this Authority in written form.

furnished subsequently to this Authority in computer readable form.

the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

Certain claims were found unsearchable (See Box I).

Unity of invention is lacking (See Box II).

4. With regard to the title,

the text is approved as submitted by the applicant.

the text has been established by this Authority to read as follows:

5. With regard to the abstract,

the text is approved as submitted by the applicant

the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No.

as suggested by the applicant.

because the applicant failed to suggest a figure

because this figure better characterizes the invention

None of the figures

## INTERNATIONAL SEARCH REPORT

International Application No.

PCT/AU 99/00691

## Box I Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
  
2.  Claims Nos.: 26-28, 31-36, 39-50, 55-58 have been partially searched  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:  
Due to the broad scope of the claims, for economic reasons the International Searching Authority only partially searched the said claims.
  
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

## Box II Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
  
4.  No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

## Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/AU 99/00691

## A. CLASSIFICATION OF SUBJECT MATTER

Int Cl<sup>6</sup>: C12N 15/12; C07K 14/435, 14/47, 14/475; A61K 39/395, 38/17

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
DERWENT DATABASES - WPAT, CHEMICAL ABSTRACTS - DGENE

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
USPM; MEDLINE; SWISS-PROT, PIR, EMBL

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
WPAT, USPM - Keywords: (transcript:(SN) factor#) and (ETS#### or ELF### or E74###) and (C12N-015/12/IC or C07K/IC or A61K/IC);

MEDLINE - Keywords: ETS and ELF, transcription factors [MESH TERM] and ETS and ELF;  
DGENE, SWISS-PROT, PIR, EMBL - Sequence search: Scq. Id. Nos: 2, 4, 7

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
1 P, X	Oncogene, 17, 1998, "A novel transcription factor, ELF5, belongs to the ELF subfamily of ETS genes and maps to human chromosome 11 p13-15, a region subject to LOH and rearrangement in human carcinoma cell lines", J. Zhou <i>et. al.</i> , pp. 2719-2732 (see entire document)	1-58
2 X	US 5 721 113 (LIBERMANN <i>et. al.</i> ) publ. 24 February 1998 (see Scq. Id. No: 4)	1, 2, 4, 6, 8, 10, 12, 15, 18, 21
3 X	Nucl. Acids Res., 25(21), 1997, "The expression of a novel, epithelium-specific ets transcription factor is restricted to the most differentiated layers of the epidermis", J. M. Andreoli <i>et. al.</i> , pp. 4287-4295 (see Fig. 2)	1, 2, 4, 6, 8, 10, 12, 15, 18, 21

Further documents are listed in the continuation of Box C

See patent family annex

\* Special categories of cited documents:

- "A" Document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
- "I" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search  
22 September 1999

Date of mailing of the international search report

-7 OCT 1999

Name and mailing address of the ISA/AU  
AUSTRALIAN PATENT OFFICE  
PO BOX 200  
WODEN ACT 2606  
AUSTRALIA  
Facsimile No.: (02) 6285 3929

Authorized officer

KAREN TAN  
Telephone No.: (02) 6283 2091

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU 99/00691

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
✓ S X	Biochem. Biophys. Res. Commun., 246, 1998, "Molecular cloning and expression of Ehf, a new member of the ets transcription factor/oncoprotein gene family", M.A. Bochert <u>et. al.</u> , pp 176-181 (see Fig. 1)	1, 2, 4, 6, 8, 10, 12, 15, 18, 21
✓ S X	AU, A, 53663/98 (THE REGENTS OF THE UNIVERSITY OF CALIFORNIA) opn. 22 June 1998, epd. 27 November 1996 (see Fig. 4)	1-5, 15
✓ S X	EP 839 908 A2 (SMITHKLINE BEECHAM CORPORATION) publ. 6 May 1988, epd. 31 October 1996 (see Fig 1b)	1, 10-13, 21, 22
✓ S X	Devlp. Biol., 151, 1992, "Isolation and characterisation of five Drosophila genes that encode an ets-related DNA binding domain", T. Chen <u>et. al.</u> , pp. 176-191 (see Fig. 2)	1, 2, 4, 6, 8, 10, 12, 15, 18, 21
✓ S X	WO 95/14773 (NORDHEIM <u>et. al.</u> ) publ. 1 June 1995, epd. 25 November 1993 (see abstract and examples)	26-28, 31-36, 39-50
✓ S X	The New Biologist, 4(5), May 1992, "Analysis of the DNA binding and transcription activation properties of the Ets 1 oncoprotein", A. Gegonne <u>et. al.</u> , pp. 512-519 (see entire document)	26-28, 31-36, 39-50
✓ S X	Hybridoma, 11(3), 1992, "Characterisation and uses of monoclonal antibody derived against DNA binding domain of the ETS family of genes", N.K. Bhat and T.S. Papas, pp. 277-294 (see entire document)	26-28, 31-36, 39-50
✓ S A	Cell Growth and Differentiation, Vol. 3, May 1992, "The ets gene family", A. Seth <u>et. al.</u> , pp. 327-334 (see entire document)	1-58
✓ S A	Eur. J. Biochem., 211, 1993, "Review: the Ets family of transcription factors", B. Wasylyk <u>et. al.</u> , pp. 7-18 (see entire document)	1-58
✓ S P,X	GenPept Database-Accession No: AAD22960, "Ets Transcription factor ESE-2a", P. Oettgen <u>et. al.</u>	1-58

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No.

PCT/AU 99/00691

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member		
AU	53663/98	WO	9823782	
EP	839908	JP	10234385	US 5789200
WO	9514773	DE	4340116	

END OF ANNEX

**PATENT COOPERATION TREATY**  
**PCT**  
**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference  2208737	<b>FOR FURTHER ACTION</b>	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).	
International application No.  PCT/AU99/00691	International filing date (day/month/year)  26 August 1999		Priority Date (day/month/year)  27 August 1998
International Patent Classification (IPC) or national classification and IPC  Int. Cl. 7 C12N 15/12; C07K 14/435, 14/47, 14/475; A61K 39/395, 38/17			
Applicant  MONASH UNIVERSITY et al			

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheet(s).</p>																	
<p>3. This report contains indications relating to the following items:</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%; text-align: right; padding-right: 5px;">I</td> <td style="width: 90%; padding-left: 5px;"><input checked="" type="checkbox"/> Basis of the report</td> </tr> <tr> <td style="text-align: right; padding-right: 5px;">II</td> <td style="padding-left: 5px;"><input type="checkbox"/> Priority</td> </tr> <tr> <td style="text-align: right; padding-right: 5px;">III</td> <td style="padding-left: 5px;"><input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: right; padding-right: 5px;">IV</td> <td style="padding-left: 5px;"><input type="checkbox"/> Lack of unity of invention</td> </tr> <tr> <td style="text-align: right; padding-right: 5px;">V</td> <td style="padding-left: 5px;"><input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: right; padding-right: 5px;">VI</td> <td style="padding-left: 5px;"><input type="checkbox"/> Certain documents cited</td> </tr> <tr> <td style="text-align: right; padding-right: 5px;">VII</td> <td style="padding-left: 5px;"><input type="checkbox"/> Certain defects in the international application</td> </tr> <tr> <td style="text-align: right; padding-right: 5px;">VIII</td> <td style="padding-left: 5px;"><input type="checkbox"/> Certain observations on the international application</td> </tr> </table>		I	<input checked="" type="checkbox"/> Basis of the report	II	<input type="checkbox"/> Priority	III	<input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	IV	<input type="checkbox"/> Lack of unity of invention	V	<input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement	VI	<input type="checkbox"/> Certain documents cited	VII	<input type="checkbox"/> Certain defects in the international application	VIII	<input type="checkbox"/> Certain observations on the international application
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VII	<input type="checkbox"/> Certain defects in the international application																
VIII	<input type="checkbox"/> Certain observations on the international application																

Date of submission of the demand  25 February 2000	Date of completion of the report  28 September 2000
Name and mailing address of the IPEA/AU  AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  JAMIE TURNER Telephone No. (02) 6283 2071

## I. Basis of the report

## 1. With regard to the elements of the international application:\*

the international application as originally filed.

the description,      pages ,      as originally filed,  
                                    pages ,      filed with the demand,  
                                    pages ,      received on      with the letter of

the claims,      pages ,      as originally filed,  
                                    pages ,      as amended (together with any statement) under Article 19,  
                                    pages ,      filed with the demand,  
                                    pages ,      received on      with the letter of

the drawings,      pages ,      as originally filed,  
                                    pages ,      filed with the demand,  
                                    pages ,      received on      with the letter of

the sequence listing part of the description:  
                                    pages ,      as originally filed  
                                    pages ,      filed with the demand  
                                    pages ,      received on      with the letter of

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

the language of publication of the international application (under Rule 48.3(b)).

the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, was on the basis of the sequence listing:

contained in the international application in written form.

filed together with the international application in computer readable form.

furnished subsequently to this Authority in written form.

furnished subsequently to this Authority in computer readable form.

The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4.  The amendments have resulted in the cancellation of:

the description,      pages

the claims,      Nos.

the drawings,      sheets/fig.

5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

## III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be nonobvious), or to be industrially applicable have not been examined in respect of:

the entire international application,  
 claims Nos: 26-28, 31-36, 39-50, 55-58

because:

the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

the description, claims or drawings (indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify):

the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

no international search report has been established for said claim Nos. 26-28, 31-36, 39-50, 55-58 when directed to the ELFS protein not comprising an Ets domain.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

the written form has not been furnished or does not comply with the standard.  
 the computer readable form has not been furnished or does not comply with the standard.

V. **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement			
Novelty (N)	Claims 7-9, 16, 17, 19, 20, 23-25, 29, 30, 37, 38, 55-58*	YES	
	Claims 1-6, 10-15, 18, 21, 22, 26-28*, 31-36*, 39-50*, 51-54	NO	
Inventive step (IS)	Claims 7-9, 16, 17, 19, 20, 23-25, 29, 30, 37, 38, 55-58*	YES	
	Claims 1-6, 10-15, 18, 21, 22, 26-28*, 31-36*, 39-50*, 51-54	NO	
Industrial applicability (IA)	Claims 1-58	YES	
	Claims	NO	

2. Citations and explanations (Rule 70.7)

\* - Note that claims 26-28, 31-36, 39-50 and 55-58 were not fully searched by the International Searching Authority. Consequently, this international preliminary examination report is established only to the extent that the invention defined by the claims is directed to the ELF5 protein comprising an Ets domain. ELF5 proteins not comprising an Ets domain have not formed any part of the basis of this report.

The abbreviations D1-D13 refer to the documents in the order as cited in the international search report.

NOVELTY (N) and INVENTIVE STEP (IS):

Documents D1 and D13 were published after the priority date but before the filing date of this international application. Unless the priority is challenged, these documents cannot form part of the prior art base under Rule 33 of the PCT.

Document D2 discloses the sequences id Nos. 3 and 4, which have over 45 % homology to the sequence id Nos. 2, 4 and 7. Consequently, the invention as defined in claims 1, 2, 4, 6, 10, 12, 14, 15, 18 and 21 is not novel and lacks an inventive step.

Document D3 discloses the sequences depicted in figure 2, which have over 45 % homology to the sequence id Nos. 3 and 4. Consequently, the invention as defined in claims 1, 2, 4, 6, 10, 12, 14, 15, 18 and 21 is not novel and lacks an inventive step.

Document D4 discloses the sequences depicted in figure 1, which have over 45 % homology to the sequence id Nos. 2, 4 and 7. Consequently, the invention as defined in claims 1, 2, 4, 6, 10, 12, 14, 15, 18 and 21 is not novel and lacks an inventive step.

Document D5 discloses the sequences depicted in figure 4 which have over 45 % homology to the sequence id Nos. 1, 2, 4 and 7. Consequently, the invention as defined in claims 1-5, 14 and 15 is not novel and lacks an inventive step.

Document D6 discloses the sequence id Nos. 1 and 2 which have over 45 % homology to the sequence id Nos. 4-7. Consequently, the invention as defined in claims 1, 10-14, 21 and 22 is not novel and lacks an inventive step.

Document D7 discloses the sequences depicted in figure 2 which have over 45 % homology to the sequence id Nos. 2, 4 and 7. Consequently, the invention as defined in claims 1, 2, 4, 6, 10, 12, 14, 15, 18 and 21 is not novel and lacks an inventive step.

-continued in supplemental box-

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

**Continuation of Box V**

Document D8 discloses proteins (and the DNA which encodes the protein) with the Ets domain and said protein binding to an Ets binding site; the protein can be used for inhibition of transcription of animal genes regulated by the Ets binding sites, eg treatment of cancer etc. As such the disclosures deprive claims 1, 14, 26-28, 31-36 and 39-50 of novelty and inventive step.

Document D9 discloses an Ets1 protein, which has the DNA binding and transcriptional activation of the Ets family. As such D9 deprives claims 1 and 14 of novelty and inventive step.

Document D10 discloses antibodies to DNA binding domain of the Ets proteins. There is no specific disclosure of any Ets protein or gene. However the monoclonal antibodies are antagonistic to Ets proteins and, as such, they can be used to modulate the ELF5 activity in a mammal. In the light of such disclosures the invention as defined in claims 26-28, 31-36 and 39-54 is not novel and lacks an inventive step.

Document D11 discloses the Ets domains of the Ets family of proteins and its use as transcriptional factors. However there is no specific disclosure relating to any use of the transcriptional role. In the light of such disclosure the invention as defined in claims 1 and 14 is not novel and lacks an inventive step.

Document D12 discloses the family of Ets proteins and their role in cellular proliferation. However the latter disclosure is primarily on the cellular level and would be insufficient to support a medical treatment based on the proteins. In the light of such disclosures the invention as defined in claim 1 and 14 is not novel and lacks an inventive step.

**INDUSTRIAL APPLICABILITY (IA):**

The invention as defined in claims 1-58 appears to be useful in regulation of cellular proliferation and leading to therapeutic and diagnostic treatment and, as such, the invention so defined would have industrial applicability.

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
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AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
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DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU 99/00691

## A. CLASSIFICATION OF SUBJECT MATTER

Int Cl<sup>6</sup>: C12N 15/12; C07K 14/435, 14/47, 14/475; A61K 39/395, 38/17

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
DERWENT DATABASES - WPAT, CHEMICAL ABSTRACTS - DGENE

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
USPM; MEDLINE; SWISS-PROT, PIR, EMBL

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
WPAT, USPM - Keywords: (transcript:(5N) factor#) and (ETS#### or ELF### or E74###) and (C12N-015/12/IC or C07K/IC or A61K/IC);  
MEDLINE - Keywords: ETS and ELF, transcription factors [MESH TERM] and ETS and ELF;  
DGENE, SWISS-PROT, PIR, EMBL - Sequence search: Seq. Id. Nos: 2, 4, 7

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	Oncogene, 17, 1998, "A novel transcription factor, ELF5, belongs to the ELF subfamily of ETS genes and maps to human chromosome 11 p13-15, a region subject to LOH and rearrangement in human carcinoma cell lines", J. Zhou <i>et. al.</i> , pp. 2719-2732 (see entire document)	1-58
X	US 5 721 113 (LIBERMANN <i>et. al.</i> ) publ. 24 February 1998 (see Seq. Id. No: 4)	1, 2, 4, 6, 8, 10, 12, 15, 18, 21
X	Nucl. Acids Res., 25(21), 1997, "The expression of a novel, epithelium-specific ets transcription factor is restricted to the most differentiated layers of the epidermis", J. M. Andreoli <i>et. al.</i> , pp. 4287-4295 (see Fig. 2)	1, 2, 4, 6, 8, 10, 12, 15, 18, 21

Further documents are listed in the continuation of Box C

See patent family annex

* Special categories of cited documents:	
"A" Document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

22 September 1999

Date of mailing of the international search report

- 7 OCT 1999

Name and mailing address of the ISA/AU

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## INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU 99/00691

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	Biochem. Biophys. Res. Commun., 246, 1998, "Molecular cloning and expression of Ehf, a new member of the ets transcription factor/oncoprotein gene family", M.A. Bochert <u>et. al.</u> , pp 176-181 (see Fig. 1)	1, 2, 4, 6, 8, 10, 12, 15, 18, 21
X	AU, A, 53663/98 (THE REGENTS OF THE UNIVERSITY OF CALIFORNIA) opi. 22 June 1998, epd. 27 November 1996 (see Fig. 4)	1-5, 15
X	EP 839 908 A2 (SMITHKLINE BEECHAM CORPORATION) publ. 6 May 1988, epd. 31 October 1996 (see Fig 1b)	1, 10-13, 21, 22
X	Devlp. Biol., 151, 1992, "Isolation and characterisation of five Drosophila genes that encode an ets-related DNA binding domain", T. Chen <u>et. al.</u> , pp. 176-191 (see Fig. 2)	1, 2, 4, 6, 8, 10, 12, 15, 18, 21
X	WO 95/14773 (NORDHEIM <u>et. al.</u> ) publ. 1 June 1995, epd. 25 November 1993 (see abstract and examples)	26-28, 31-36, 39-50
X	The New Biologist, 4(5), May 1992, "Analysis of the DNA binding and transcription activation properties of the Ets 1 oncoprotein", A. Gegonne <u>et. al.</u> , pp. 512-519 (see entire document)	26-28, 31-36, 39-50
X	Hybridoma, 11(3), 1992, "Characterisation and uses of monoclonal antibody derived against DNA binding domain of the ETS family of genes", N.K. Bhat and T.S. Papas, pp. 277-294 (see entire document)	26-28, 31-36, 39-50
A	Cell Growth and Differentiation, Vol. 3, May 1992, "The ets gene family", A. Seth <u>et. al.</u> , pp. 327-334 (see entire document)	1-58
A	Eur. J. Biochem., 211, 1993, "Review: the Ets family of transcription factors", B. Wasylyk <u>et. al.</u> , pp. 7-18 (see entire document)	1-58
P,X	GenPept Database-Accession No: AAD22960, "Ets Transcription factor ESE-2a", P. Oettgen <u>et. al.</u>	1-58

# INTERNATIONAL SEARCH REPORT

International Application No.

PCT/AU 99/00691

## Box I Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
  
2.  Claims Nos.: 26-28, 31-36, 39-50, 55-58 have been partially searched because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:  
Due to the broad scope of the claims, for economic reasons the International Searching Authority only partially searched the said claims.
  
3.  Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

## Box II Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
  
4.  No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

The additional search fees were accompanied by the applicant's protest.  
 No protest accompanied the payment of additional search fees.

**INTERNATIONAL SEARCH REPORT****Information on patent family members**

International application N .

**PCT/AU 99/00691**

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member		
AU	53663/98	WO	9823782	
EP	839908	JP	10234385	US 5789200
WO	9514773	DE	4340116	

**END OF ANNEX**